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 AT ABINGDON, VA
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 2/11/2020
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**UNITED STATES DISTRICT COURT
 WESTERN DISTRICT OF VIRGINIA
 ABINGDON**

UNITED STATES OF AMERICA)
) **Criminal No. 1:20CR00007**
v.)
) **Violations: 21 U.S.C. §§ 331(a),**
ANIMAL HEALTH INTERNATIONAL, INC.) 333(a)(1), and 352(f)(1)

INFORMATION

INTRODUCTION

1. Defendant Animal Health International, Inc. (“AHI”) is a Colorado corporation with its principal place of business in Colorado. AHI is comprised of two legacy organizations, Lextron, Inc. (“Lextron”) and Walco International, Inc. (“Walco”). In June 2011, Lextron acquired all outstanding stock of the parent company of Walco and changed its name to AHI. Walco continued operations as a subsidiary of AHI until December 2011 when Animal Health Holdings, Inc. and each of its wholly-owned subsidiaries, including Walco, were merged with and into AHI and no longer had separate corporate existences. AHI, and its predecessor entities, dispense, distribute and sell, among other products, veterinary prescription drugs to customers in the production animal industry across the United States. Specifically, AHI obtains prescription drugs for production animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other distribution facilities.

2. The Food and Drug Administration (“FDA”) of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* (“FDCA”). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful

effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear “adequate directions for use.” 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as “directions under which the *layman* can use a drug safely and for the purposes for which it is intended.” 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D (“Exemptions from Adequate Directions for Use”).

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian’s professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2).

5. The FDCA's restrictions on veterinary prescription drugs are not primarily to protect animals from the potential harms of prescription drugs, but are to protect the human food supply from unsafe drug residues in the edible tissues of animals sold for slaughter. Common causes of illegal residues include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residues in the nation's drug supply are concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

6. Certain legacy customers of AHI, namely Marlin Webb and Billy K. Groce, were not properly licensed to receive, transport, store, distribute, or dispense veterinary prescription drugs in the Commonwealth of Virginia from January 2012 through April 2015.

7. Webb was the store manager of a cooperative in Hillsville, Virginia. The cooperative was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Webb operated a side business from the cooperative's location in which he illegally circumvented the FDA's regulation of veterinary prescription drugs by illegally obtaining from Billy K. Groce and AHI and reselling veterinary prescription drugs using unlawful prescriptions written by a veterinarian who was licensed in Tennessee but who was not properly licensed to

practice veterinary medicine in Virginia and who did not have a veterinarian-patient relationship with the animals in question. That veterinarian died in 2015.

8. Groce was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Groce operated an unlicensed veterinary prescription drug distribution business. Groce worked with the same veterinarian as did Webb.

9. Webb and Groce obtained veterinary prescription drugs from AHI in interstate commerce without valid prescriptions, and, on many occasions, with no prescription at all.

10. On April 29, 2015, the government executed search warrants at locations in Virginia and Tennessee associated with Groce and Webb. In 2016 and 2017, respectively, Groce and Webb pled guilty to illegally conspiring to defraud the FDA by obtaining and distributing veterinary prescription drugs from July 2009 through April 29, 2015 in a manner that circumvented the FDA's regulation of veterinary prescription drugs.

11. Groce and Webb were legacy customers of, among others, Lextron and Walco, and continued to be customers after the companies merged to form AHI in 2012 until May 2015. Neither Lextron, Walco, nor AHI performed adequate customer diligence processes, nor adequately trained sales representatives to raise questions regarding Groce's, Webb's or the veterinarian's activities in Virginia and Tennessee. For example, Groce operated a business that stored and distributed veterinary prescription drugs out of a storefront called "Goin' Postal" and his personal residence. Neither of those locations resembled a veterinarian establishment and should have raised questions for sales representatives who personally visited them. After learning of search warrants executed on each of the customers' locations, AHI took some steps to block the sale of veterinary prescription drugs to these customers on May 4, 2015.

12. Furthermore, between January 2012 and May 2015, AHI did not maintain the proper licenses to ship from its Memphis, Tennessee, facility into Virginia or from its Wolcott, Indiana, facility into Virginia or Tennessee, but, despite this deficiency, shipped products from those locations to Virginia and Tennessee.

13. All veterinary prescription drugs distributed by AHI to Groce and Webb were misbranded because, neither recipient was licensed to possess or distribute veterinary prescription drugs, and the prescribing veterinarian was not properly licensed to practice veterinary medicine in Virginia and consequently none of the drugs he caused to be dispensed were prescribed pursuant to lawful orders.

14. From the illegal shipments to and on behalf of Groce and Webb, AHI received \$7,427,928 (seven million four hundred twenty-seven thousand nine hundred twenty-eight dollars) and made a profit of \$558,309 (five hundred fifty-eight thousand three hundred nine dollars) by unlawfully distributing veterinary prescription drugs to or on behalf of Groce and Webb.

15. From 2012 through on or about 2018, AHI caused additional misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal and, in some instances, by shipping veterinary prescription drugs to locations in states in which AHI did not have legal authority to make such shipments. AHI obtained not less than \$46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

16. The Information is realleged and incorporated by reference into this Count.

17. From about January 2012 to April 2015, in the Western District of Virginia, Animal Health Incorporated (“AHI”) introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs’ labeling did not bear adequate directions for the use of such drugs.

18. The offense conduct included, but was not limited to, the following:

a. AHI distributed veterinary prescription drugs directly to Billy K. Groce and Marlin Webb, notwithstanding that neither Groce nor Webb was legally authorized to possess or distribute the drugs; and

b. AHI distributed veterinary prescription drugs to customers of Billy K. Groce and Marlin Webb without a lawful prescription having been issued for those drugs.

19. Since these veterinary prescription drugs were not lawfully distributed or prescribed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

20. Upon conviction of the offense alleged in this Information, AHI shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of AHI’s conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

21. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of \$46,802,203 pursuant to 21 U.S.C. § 853(p).

DATED: February 11, 2020

for Randy Ramczyk
THOMAS T. CULLEN
United States Attorney